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Food and Drug Administration Office of Nutritional Products, Labeling & Dietary Supplements (HFS-810) 5100 Paint Branch Parkway College Park, MD 20740

July 26, 2005

## RE: Dietary Supplement Claims Notification

## Dear Sir/Madam:

This letter is to notify the Food and Drug Administration (FDA) that the following product is manufactured, packed and/or distributed by Hillestad Pharmaceuticals at 178 US Highway 51N, Woodruff, WI 54568. This notification is being provided pursuant to 21 U.S.C. 343(r)(6) and 21 CFR 101.93(a).

## Product Name: Hawthorn Berries

The following statement(s) are or may be used on the labels and in the labeling of the product:

"Hawthorn Berries are rich in bioflavonoids. Hawthorn Berries may help support a healthy cardiovascular system."

I certify that the information in this notice is complete and accurate and that Hillestad Pharmaceuticals has substantiation that the statements are truthful and not misleading.

Sincerely,

Dan Hillestad

President

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